

PATENT COOPERATION TREATY

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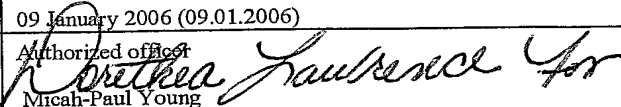
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

MAILED 02 FEB 2006

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|--|--|--|-----------------------|-------------------------------------|-----------|---------------------|--------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|-------------------------------------|--------------|---|
| Applicant's or agent's file reference 13-002 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 | | | | | | | | | | | | | | | | | | | | | | | | |
| International application No. PCT/US05/09548 | International filing date (day/month/year) 24 March 2005 (24.03.2005) | Priority date (day/month/year) 31 March 2004 (31.03.2004) | | | | | | | | | | | | | | | | | | | | | | | | | |
| International Patent Classification (IPC) or national classification and IPC IPC(8): A61K 9/10 and US Cl.: 424/439 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Applicant SOLTERO, RICHARD | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | | | | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date of submission of the demand 13 October 2005 (13.10.2005) | | Date of completion of this report 09 January 2006 (09.01.2006) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | | <div style="text-align: center;">  Authorized officer Micah-Paul Young </div> Telephone No. (571) 272.1600 | | | | | | | | | | | | | | | | | | | | | | | | | |

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/09548

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
 pages 1-9 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the claims:
 pages 10-12 as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the drawings:
 pages NONE as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/figs NONE
- ☒ the sequence listing (*specify*): NONE
- ☒ any table(s) related to the sequence listing (*specify*): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/09548**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-27</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-27</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-27</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Claims 1, 2, 5, 9, 12-21 and 23-27 lack novelty under PCT Article 33(2) as being anticipated by YANG et al (US 4,950,689). See entire document including the examples. The reference shows a pectin gel matrix comprised of active ingredients and optional excipients. The gel is formulated in a manner such that it has a texture that enables easy swallowing. Particular drugs include those derived from plants are shown in column 4, line 29 column 5, line 19.

Claims 1-5, 10, 12-21 and 23-27 lack novelty under PCT Article 33(2) as being anticipated by ROYER US 5,783,214. The reference shows a matrix comprised of gelatin and hyaluronic acid wherein the gelatin consists of type A and B having a Bloom Value of 60-300. The matrix may be orally administered. Columns 3-5. Particular drug formulations are shown in columns 7-9.

Claims 1-27 lack novelty under PCT Article 33(2) as being anticipated by BUEHLER et al US 6,432,442. See examples 1-2. The reference shows gelatin matrices wherein the Bloom Value is from what about 150 to about 350. The matrices are formulated for improved texture and ease of administration. The matrices may further comprise hydroxypropyl cellulose, agar and other matrix forming gels. See detailed Description of the invention. The matrices comprise active agents, including plant extracts such as St. John's Wort.

Claims 1, 2, 5, 8, 12-21 and 23-27 lack novelty under PCT Article 33(2) as being anticipated by LUBER et al US 2003/0175336 A1. See examples 1-3, claims 1-11. The reference shows a polyethylene oxide matrix formulated for ease in swallowing. See [0014], [0035]. Particular active agents including herbal extracts are shown in sections [0016], [0020].

Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/09548

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 16, 18, 20, 22, 24 and 26 objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): For claims 16 and 18 reciting a broad range followed by linking terminology "such as" and then a narrow range makes it unclear as to what the intended limits of the claims are. The terminology does not set forth the subject matter in a clear and concise manner.

The terminology in claims 20, 22, 24 and 26 "selected from the group comprising" rather than "selected from the group consisting of" is confusing in that it is an improper representation of the group of elements.